IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

LIVINRITE, INC., **Plaintiff,**	)	
v.	)	**Civil Action No. 1:18-cv-00603**
ALEX M. AZAR, II, *Secretary of the United States Department of Health and Human Services,* **Defendant.**	)	

MEMORANDUM OPINION

Plaintiff, a Medicare-certified home health services provider, brings this action against defendant, the Secretary of the United States Department of Health and Human Services ("the Secretary"), seeking reversal of a decision by the Medicare Appeals Council ("MAC") that plaintiff had been overpaid approximately $1 million for Medicare claims submitted from 2008 to 2010. Specifically, plaintiff challenges the MAC's determinations

(i) that ten claims submitted by plaintiff were not covered by Medicare,

(ii) that a valid statistical sampling methodology was used to derive through extrapolation plaintiff's total overpayment amount, and

(iii) that plaintiff was not entitled to a waiver of liability for the overpayment amount.

In response, defendant argues that the MAC's decision passes muster under the deferential standard of review prescribed by the Administrative Procedures Act ("APA")[1] because each of the MAC's conclusions applied the correct legal standards and is amply supported in the record.

At issue in this matter are the parties' cross-motions for summary judgment, which have been fully briefed and argued and are thus ripe for decision.

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[1] 5 U.S.C. § 701 *et seq.*

I.

The APA confines judicial review of agency decisions to the administrative record of proceedings before the agency. *See* 5 U.S.C. § 706; *see also Camp v. Pitts*, 411 U.S. 138, 142 (1973). Put another way, "when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). Given the district court's limited role in reviewing the administrative record, the ordinary summary judgment standard does not apply. The key difference in an APA case is that "the presence or absence of a genuine dispute of material fact is not in issue, as the facts are all set forth in the administrative record." *Hyatt v. U.S. Patent & Trademark Office*, 146 F. Supp. 3d 771, 780 (E.D. Va. 2015). Therefore, in a review of agency action under the APA, "[t]he 'entire case' on review is a question of law." *Am. Bioscience, Inc.*, 269 F.3d at 1083.

The administrative record pertaining to plaintiff's administrative appeal proceeding before the MAC reflects the following relevant facts.[2]

- On March 11, 2010, AdvanceMed, a Centers for Medicare and Medicaid Services ("CMS") contractor, opened an investigation based on a complaint that plaintiff was (i) admitting patients who did not qualify for home health services and (ii) continuing to provide physical therapy to patients even after those patients reached their maximum level of potential. In addition, AdvanceMed conducted preliminary data analysis that showed plaintiff ranked above average in peer comparison of Medicare billing. After determining that a full audit of all claims paid to plaintiff would not be feasible, AdvanceMed conducted a statistical sampling of the Medicare claims paid to plaintiff. In this respect, AdvanceMed reviewed the services provided by plaintiff to 30 randomly selected beneficiaries and then extrapolated the overpayment determinations to estimate the total amount plaintiff was overpaid by Medicare.
- AdvanceMed selected January 1, 2008 to June 30, 2010 as the period to be reviewed and used simple random sampling as the sample design. AdvanceMed defined the universe as all fully and partially paid claims submitted by the provider for the period covered. It

[2] The administrative record also contains a substantial amount of evidence, such as the services provided by plaintiff and the beneficiaries' conditions, that is relevant to the ten individual claim denials that plaintiff challenges in this action. Instead of listing that evidence here, the record evidence underlying the ten Medicare claims will be referenced, when necessary, in the below discussions of whether such claim denials by the MAC were supported by substantial evidence in the record.

defined the sampling unit as individual beneficiaries, with each unit identified by a health insurance claim ("HIC") number. AdvanceMed created the sampling frame by identifying those sampling units from the universe where at least one line of service on the claim was paid greater than $0 to the provider, and then sorted the frame by HIC number. The frame included 1,717 units.

- AdvanceMed then used a random number-generator software to draw a simple random sample of 30 beneficiaries.
- Fifteen of the 1,717 HIC numbers used in the sampling frame to identify the beneficiaries did not match the beneficiaries' actual HIC numbers.
- On October 14, 2010, AdvanceMed requested documentation from plaintiff to support 60 Medicare claims plaintiff had submitted and received reimbursement for on behalf of those 30 beneficiaries. AdvanceMed used the documentation to conduct a medical review of those claims and determined that plaintiff had been overpaid for 33 claims not covered by Medicare. Using the lower limit of the 90% two-sided confidence interval,[3] AdvanceMed then extrapolated the sampled overpayment to conclude that plaintiff had received a total overpayment of $2,775,432.
- On June 6, 2012, AdvanceMed provided Plaintiff with documentation supporting its overpayment extrapolation, including, *inter alia*, documentation of the sample design, the universe of claims, the sampling frame, the random numbers used, the random sample generated, and the statistical results.
- After receiving notice of the overpayment assessment, plaintiff sought redetermination of AdvanceMed's determination that the 33 claims were not covered. The resulting decision was partially favorable, as AdvanceMed reversed 2 of the claim denials. Plaintiff then requested reconsideration by a separate CMS contractor, which affirmed all 31 of the claim denials.
- Next, plaintiff requested and received a hearing before an Administrative Law Judge ("ALJ"). At the hearing, plaintiff both challenged AdvanceMed's individual claim denials and argued that AdvanceMed's statistical sampling could not be replicated based on the documentation provided by AdvanceMed. The ALJ rejected plaintiff's challenge to AdvanceMed's statistical sampling, but reversed certain claim denials.
- Finally, plaintiff requested review of the ALJ's decision by the MAC, which constituted the final stage of administrative review. On March 29, 2018, the MAC issued a decision that reversed 3 claim denials by the ALJ but affirmed the ALJ's conclusions with respect to the validity of AdvanceMed's statistical sampling and the remaining 15 claim denials.

[3] Using the lower limit of the confidence interval means that there is a 90% likelihood that the extrapolated overpayment amount is less than the actual overpayment amount made to the provider. *See* Medicare Program Integrity Manual Ch. 8 § 8.4.5.1

II.

The standards of review that govern the district court's review of the MAC's final decision are set forth in the Medicare statute and the APA. First, the Medicare statute provides that the MAC's factual findings must be upheld "if supported by substantial evidence." 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A). The scope of review of the MAC's factual findings under this standard is quite limited. As the Supreme Court has explained, substantial evidence "does not mean a large or considerable amount of evidence, but rather 'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Pierce v. Underwood*, 487 U.S. 552, 565 (1988) (quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938)). And importantly, the district court may not "reweigh conflicting evidence, make credibility determinations, or substitute [its] judgment for that of the [MAC]." *Johnson v. Barnhart*, 434 F.3d 650, 653 (4th Cir. 2005); *see Jarvis v. Berryhill*, 697 F. App'x 251, 252 (4th Cir. 2017) ("The duty to resolve conflicts in the evidence rests with the [agency], not with a reviewing court.").

Second, pursuant to the APA, the MAC's decision may be set aside only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The Fourth Circuit has made clear that "[r]eview under this standard is highly deferential, with a presumption in favor of finding the agency action valid." *Ohio Vall. Envt'l Coalition v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009). In general, an agency decision will not be considered arbitrary and capricious as long as "the agency has examined the relevant data and provided an explanation of its decision that includes 'a rational connection between the facts found and the choice made.'" *Id.* at 192–93 (quoting *Motor Veh. Mfrs. Ass'n v. State Farm Mut. Ins. Co.*, 463 U.S. 29, 43 (1983)).

III.

Before applying these standards of review to the MAC's decision, it is important to describe briefly the statutory and regulatory framework that governs the MAC's determination whether a healthcare provider was overpaid by Medicare.

Medicare is a federal health insurance program for the elderly and disabled that is administered by the Secretary through CMS. Among other things, the Medicare program reimburses providers of certain medical and health services for the cost of services that are covered by the Medicare Act. *See* 42 U.S.C. § 1395 *et seq.* To promote the integrity of the Medicare program, the Secretary is authorized to enter into contracts with private entities to review claims for reimbursement submitted by providers, to determine whether Medicare payments should not be, or should not have been, made, and to recoup payments that should not have been made. *Id.* § 1395ddd; 42 C.F.R. § 405.371(a)(3). In light of the substantial volume of Medicare claims submitted by providers, Medicare contractors are permitted to use statistical sampling and extrapolation to determine the extent to which a provider was overpaid by Medicare. *See* CMS Ruling 86-1 at 11 (Feb. 20, 1986).

Pursuant to the Medicare Program Integrity Manual ("MPIM"), a Medicare contractor must follow six steps to conduct statistical sampling for overpayment calculation. MPIM Ch. 8 § 8.4.1.3 (Pub. No. 100-08, Rev. 377) (2011). First, the contractor must select the provider to be reviewed. *Id.* Second, the contractor must select the period to be reviewed. *Id.* §§ 8.4.1.3, 8.4.3.1. Third, the contractor must define the universe, the sampling unit, and the sampling frame. *Id.* § 8.4.1.3. The "universe" consists of all Medicare claims submitted by the provider during the period under review. *Id.* § 8.4.3.2.1. The "sampling unit" is the element that will be reviewed (*e.g.*, individual claims or beneficiaries). *Id.* § 8.4.3.2.2. The "sampling frame" is the group of sampling units that

remain after any limiting criteria are applied to the sampling universe. *Id.* § 8.4.3.2.3. Fourth, the contractor must choose a sampling method and implement the method to select the sample. *Id.* § 8.4.1.3. The sampling method that is used must be classified as "probability sampling," that is, (i) the method must be capable of selecting a set of enumerable, distinct samples from the sampling frame and (ii) each sampling unit must have a known probability of being selected that is greater than zero.[4] Fifth, the contractors must review each unit in the selected sample and determine if an overpayment has been made. *Id.* §§ 8.4.1.3, 8.4.6.3. Sixth, the contractor must estimate the total overpayment to the provider during the review period by extrapolating the results from the selected sample to the entire sampling frame. *Id.* §§ 8.4.1.3, 8.4.5.

A provider may challenge a Medicare contractor's calculation of overpayment through the administrative appeals process.[5] The use of statistical sampling by the contractor "creates a presumption of validity as to the amount of an overpayment." CMS Ruling 86-1 at 11. It is the provider's burden to overcome this presumption by demonstrating either (i) that the sample is not statistically valid or (ii) that the contractor's determinations of overpayment with respect to specific units in the selected sample are incorrect. *Id.*

First, the provider may challenge the statistical validity of the sample selected by the contractor. A challenge to the validity of the sample "must be predicated on the actual statistical validity of the sample as drawn and conducted." MPIM § 8.4.1.1. Accordingly, "[i]f a particular probability sample design is properly executed" in accordance with the six steps set forth above,

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[4] The MPIM recognizes various valid sampling methods, including simple random sampling, systematic sampling, stratified sampling, and cluster sampling. MPIM § 8.4.4.1. If the contractor selects the simple random sampling method, as did AdvanceMed, the contractor must select a fixed number of sampling units from the sampling frame at random and may not allow the same unit to be selected more than once. *Id.* § 8.4.4.1.1.

[5] As set forth in the regulations, the Medicare appeals process consists of (i) redetermination by a Medicare contractor, (ii) reconsideration by a Qualified Independent Contractor, (iii) a hearing before an Administrative Law Judge of the Department of Health and Human Services, and finally (iv) review by the MAC. *See generally* 42 C.F.R. §§ 405.940–405.1140.

"then assertions that the sample and its resulting estimates are 'not statistically valid' cannot legitimately be made." *Id.* § 8.4.2. Put simply, "a probability sample and its results are always 'valid.'" *Id.*

Second, the provider may challenge the contractor's determination that certain sampling units in the selected sample are not covered by the Medicare Act and thus resulted in an overpayment to the provider. In this respect, home health services qualify for Medicare coverage if such services are "reasonable and necessary" and are provided to a beneficiary who is (i) confined to the home, (ii) under the care of a physician who establishes a plan of care in accordance with 42 C.F.R. § 409.43, and (iii) in need of "skilled services" as certified by a physician. 42 U.S.C. §§ 1395f(a)(2)(C), 1395y(a)(1)(A); 42 C.F.R. § 409.42. A skilled service is one that is "so inherently complex that it can be safely and effectively performed only by, or under the supervision of, professional or technical personnel." 42 C.F.R. § 409.32

IV.

Plaintiff first argues that the MAC's decision should be set aside because the MAC's decision that AdvanceMed's sampling methodology could be accurately replicated is arbitrary and capricious, incorrectly applies the relevant legal standards, and is not supported by substantial evidence in the record. Notably, plaintiff does not challenge the MAC's determination that the sampling methodology applied by AdvanceMed was statistically valid.[6] Rather, plaintiff's argument, distilled to its essence, is that AdvanceMed's extrapolated overpayment determination must be invalidated because it is impossible to replicate the sample based on the materials in the record.

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[6] Nor could such a challenge be legitimately made. As reflected in the record, AdvanceMed followed the six steps for sampling listed in MPIM § 8.4.1.3, and used a simple random sampling method to produce a "probability sample." Accordingly, there is no basis on which plaintiff might contend that the methodology used and the estimate it produced were statistically invalid. *See* MPIM § 8.4.2.

In addition to providing contractors with instructions on the proper execution of statistical sampling for overpayment calculation, the MPIM also requires Medicare contractors to document the sampling methodology, the sampling universe and frame, and the random number selection process that were used to estimate overpayment. MPIM §§ 8.4.4.2, 8.4.4.4, 8.4.4.4.1, 8.4.4.4.3. The purpose of these documentation requirements is to ensure that the sampling frame and the sample can be replicated in the event that the methodology is challenged. *Id.* §§ 8.4.4.2, 8.4.4.4.1. As previous MAC decisions have concluded, failure to supply the provider with sufficient documentation to recreate the sampling frame and sample effectively deprives the provider of its right to challenge the statistical validity of the sample and thus may constitute a ground for invalidating the overpayment extrapolation. *See William Vecchioni, D.C.*, M-13-3700 (H.H.S. Nov. 20, 2013); *Global Home Care, Inc.*, M-11-116 (H.H.S. Jan. 11, 2011); *Podiatric Medical Associates*, M-10-230 (H.H.S. June 22, 2010).

But here, as the MAC concluded, plaintiff was provided with ample documentation to enable plaintiff to replicate the sampling frame and the sample. The record confirms that the statistical sampling information CMS provided to plaintiff included, *inter alia*, an electronic spreadsheet of the frame used in the overpayment review; a memorandum explaining the universe, sampling frame, sampling unit, sample size, and sample design; the sample that was selected from the frame; and the exact random numbers that were generated and used to select the sample from the frame. And it is undisputed that applying the random numbers provided by CMS to the sampling frame provided by CMS would generate the same sample as the one selected and recorded by AdvanceMed. Thus, it is clear that the MAC's conclusion that plaintiff had sufficient records to replicate the results of AdvanceMed's sampling was rational and based on substantial evidence in the record.

Seeking to avoid this conclusion, plaintiff argues that it was not possible to replicate the sampling frame and sample provided by CMS because 15 of the 1,717 HIC numbers[7] used to identify the beneficiaries listed in the sampling frame were not the beneficiaries' actual HIC numbers and did not comply with CMS guidelines governing the proper formatting of HIC numbers. According to plaintiff, if the beneficiaries' actual HIC numbers were used, the order of the sampling units—*i.e.*, the beneficiaries—would have been different in the sampling frame and thus application of the random numbers provided by CMS would have generated a sample different from the one selected by AdvanceMed. This argument is entirely unpersuasive. Plaintiff had sufficient documentation to replicate the sampling frame because it was provided with the exact sampling frame used by AdvanceMed. And plaintiff had sufficient records to replicate the sample because it had the exact random numbers and frame used by AdvanceMed and the actual sample AdvanceMed selected. Indeed, it was not necessary for plaintiff to create a new frame in which plaintiff replaced certain HIC numbers because it is undisputed that the HIC numbers in the frame served only as placeholders to identify the sample units (*i.e.* the beneficiaries) and that changing the HIC numbers did not impact the probability that any particular beneficiary would be randomly selected.[8] In short, it is immaterial that a few of the HIC numbers used in the frame did not match the beneficiaries' actual HIC numbers.

Accordingly, plaintiff has cited no persuasive basis on which to call into question the MAC's conclusion that plaintiff was provided with sufficient documentation to replicate the frame

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[7] A HIC number is a unique alphanumeric identifier assigned to Medicare beneficiaries by CMS, the Social Security Administration, and the Railroad Retirement Board. HIC numbers are used to identify beneficiaries in Medicare's systems and by providers when billing for services rendered to beneficiaries. *See* Medicare General Information, Eligibility, and Entitlement Manual Ch. 2 § 50.

[8] In addition, it is undisputed that plaintiff was able to identify the beneficiaries based on the HIC numbers used in the sampling frame. Thus, plaintiff was also able to challenge AdvanceMed's coverage determinations with respect to the selected beneficiaries.

and sample and to test the statistical validity of AdvanceMed's sampling methodology. The MAC thus sensibly and correctly denied plaintiff's claim that AdvanceMed's sampling and extrapolation results must be discarded for lack of documentation. *See Pruchniewski v. Leavitt*, No. 8:04 CV 2200 T 23TBM, 2006 WL 2331071, at *13 (M.D. Fla. Aug. 10, 2006) (holding that there was substantial evidence to support the agency's conclusion that the plaintiff did not demonstrate grounds to discard the sample audit by reason of a lack of documentation because "there was adequate documentation and information available to the Plaintiff to permit him to test the reliability of this audit").

V.

Next, plaintiff argues that the MAC's determinations that certain claims selected for review did not qualify for Medicare coverage should be set aside because those decisions are arbitrary and capricious, incorrectly apply the relevant legal standards, and are not supported by substantial evidence.[9] Each of the ten coverage determinations challenged by plaintiff are discussed separately below.

A. Beneficiary: C.A., Dates of Service: January 13, 2010 – March 12, 2010

Plaintiff argues that the MAC's determination that there was no Medicare coverage for the occupational therapy visit to C.A. performed on March 12, 2010 must be set aside because the MAC did not give a sufficient explanation for its decision. A review of the MAC's decision demonstrates that the MAC provided an adequate explanation for its decision.

The Fourth Circuit has explained that an agency satisfies its duty under the APA to give an adequate explanation for its decision "[i]f a reviewing court can discern what the [agency] did and

[9] Specifically, plaintiff's challenge is aimed at 10 of the 15 claims for which the MAC concluded there was no coverage.

why [it] did it." *Piney Mountain Coal Co. v. Mays*, 176 F.3d 753, 762 n.10 (4th Cir. 1999) (internal quotation marks omitted). In short, the "duty of explanation is not intended to be a mandate for administrative verbosity or pedantry." *Id.* Here, the reasons and evidence relied upon to support the MAC's no-coverage determination are entirely discernable; it is clear that the MAC concluded the occupational therapy visit at issue was not necessary because C.A. had already met the goals of her therapy and was following the HEP on prior visits. In this respect, the MAC decision first explained that the ALJ had found that the March 12, 2010 visit to go over the home exercise program ("HEP") was not necessary and did not require the skills of an occupational therapist because C.A.'s therapist had already determined on March 9, 2010 that C.A. had met the goals of her therapy and was following the HEP. The decision next noted plaintiff's argument in response that the visit was necessary to give further instructions and perform a final assessment. The MAC then examined the medical records from each of C.A.'s occupational therapy visits, including clinical notes reflecting that C.A. had been instructed on the HEP on multiple visits and that as of March 9, 2010, C.A. was following the home exercise program and was benefitting from energy-conservation techniques. After reciting this evidence, the MAC decision stated that it agreed with the ALJ's determination that the occupational therapy service provided on March 12, 2010 was not necessary. It is clear from the MAC decision, then, that the MAC affirmed the ALJ's determination that the March 12, 2010 visit was unnecessary—and rejected plaintiff's argument to the contrary—because the record as a whole supported the ALJ's findings that C.A. had already met the goals of her therapy and was following the HEP on prior visits. Accordingly, the MAC's no-coverage determination with respect to C.A.'s March 12, 2010 visit satisfies the MAC's duty of explanation under the APA; a reviewing court "can discern what the [MAC] did and why." *Piney Mountain*, 176 F.3d at 762 n.10.

B. Beneficiary: D.B., Dates of Service: December 9, 2009 – February 26, 2010

Plaintiff argues that the MAC's determinations that there was no Medicare coverage for the nursing, occupational therapy, and physical therapy services provided to D.B. must be set aside because the MAC did not give a sufficient explanation for its determinations and because those determinations are not supported by substantial evidence.[10] A review of the MAC's decision demonstrates that the MAC sufficiently explained the reasoning for its determinations of no-coverage and that such determinations are supported by substantial evidence in the record.

First, the MAC adequately explained that the nursing services provided to D.B. during the period at issue were not covered by Medicare because D.B. did not require skilled nursing services for purposes of observing or assessing D.B. Earlier in its decision, the MAC stated that the Medicare Benefits Policy Manual Ch. 7 ("MBPM") § 40.1.2.1 provides that observation and assessment of a patient by a nurse are necessary when the likelihood of change in a patient's condition requires skilled nursing personnel to evaluate the patient's need for modification of treatment until the patient's treatment regimen is stabilized. Thus, it is clear that the MAC's analysis of the necessity of D.B.'s assessment and observation services was focused on whether the record evidence reflected a sufficient likelihood of change in D.B.'s respiratory condition to warrant such services. In this respect, the MAC decision reviewed the record evidence and noted that prior to the commencement of the services at issue, D.B.'s vitals were within normal limits, her respiratory system and skin were normal, and she was alert. The MAC also acknowledged the evidence emphasized by plaintiff, namely documentation of fluctuations in D.B.'s blood pressure readings and pain levels and a change in medication. The MAC's review of this evidence makes

[10] It does not appear that plaintiff challenges the MAC's determination that there was no coverage for the wound care services provided to D.B. during this period.

clear that the MAC determined that the record evidence, as a whole, did not show that there was a sufficient likelihood of change in D.B.'s condition to create a necessity for observation and assessment services by a skilled nurse. Accordingly, the MAC's no-coverage determination with respect to D.B.'s observation and assessment services satisfies the MAC's duty of explanation under the APA.

In addition, the MAC's determination that there was an insufficient likelihood of change in D.B.'s condition to justify observation and assessment services by a nurse is supported by substantial evidence in the record. As noted above, the record evidence reflects that before the observation and assessment services at issue were provided, D.B.'s vitals were within normal limits, her respiratory system and skin were normal, and she was alert. This evidence satisfies the substantial evidence standard because it is certainly sufficient to allow "a reasonable mind [to] accept as adequate to support [the] conclusion" that there was an insubstantial likelihood that D.B.'s respiratory condition would change. *See Pierce*, 487 U.S. at 565. It is true, as plaintiff points out, that the record also contains evidence that during this time, D.B.'s blood pressure readings and pain levels fluctuated and that D.B.'s medication changed.[11] But it is well-settled that "[t]he duty to resolve conflicts in the evidence rests with the [agency], not with a reviewing court." *Smith v. Chater*, 99 F.3d 635, 638 (4th Cir. 1996). And the evidence highlighted by plaintiff is not so compelling as to overwhelm the evidence relied upon by the MAC. *See Musgrave v. Sullivan*, 966 F.2d 1371, 1374 (10th Cir. 1992) (holding that "[e]vidence is not substantial if it is overwhelmed by other evidence in the record"). Accordingly, the MAC's determination that there was an

[11] Plaintiff also argues that there is evidence that D.B. was admitted to the hospital on January 23, 2010 for wheezing breath sounds. But the record evidence reflects that this occurred after D.B.'s last nursing visit. Thus, this evidence does not weigh against the MAC's determination that there was an insufficient likelihood of change in D.B.'s condition during the period at issue to justify observation and assessment services by a nurse.

insufficient likelihood of change in D.B.'s condition to justify observation and assessment services by a nurse is supported by substantial evidence in the record.

The MAC also determined that the occupational therapy and physical therapy services provided to D.B. during the period at issue were not covered by Medicare because there was no reasonable expectation of material improvement in a reasonable and predictable period of time, as is required for Medicare coverage. *See* MBPM § 40.2.1. In its decision, the MAC discussed evidence of multiple occasions on which D.B. expressed a persistent lack of desire to participate in therapy and refused to perform exercises. Thus, the MAC's decision passes muster under the APA because it adequately explained that the determination that it was not reasonable to expect that the therapy services at issue would result in improvement was based on evidence that D.B. lacked a desire to participate in therapy and because that determination is supported by substantial evidence in the record.

C. Beneficiary: M.G., Dates of Service: September 11, 2009 – November 11, 2009

Plaintiff argues that the MAC's determinations that there was no Medicare coverage for the services provided to M.G. must be set aside because the MAC's decision is not supported by substantial evidence in the record. A review of the MAC's decision and the record evidence demonstrates that the MAC's determination of no-coverage is supported by substantial evidence.

The MAC determined that the services provided to M.G. during the period at issue were not covered by Medicare because the plan of care for such services did not meet the requirements of 42 C.F.R. § 409.43(e), which provides that the plan of care "must be reviewed by the physician . . . at least every 60 days" and that each review "must contain the signature of the physician who reviewed it and the date of review." According to the MAC decision, the plan of care for the period at issue was signed by a nurse practitioner, not a reviewing physician. Plaintiff argues that this

factual determination is incorrect because the record evidence contains a copy of the plan of care that is countersigned by a physician and an affidavit from the physician explaining that she co-signed the plan of care along with the nurse practitioner. In response, defendant argues that even if the copy of the plan identified by plaintiff undermines the evidentiary basis for the MAC's finding that the plan was not signed by a physician, substantial evidence nonetheless exists to support the MAC's alternative determination that the plan failed to comply with § 409.43(e) because the physician did not review the plan every 60 days.

Defendant's argument is correct; although the MAC's decision was not "a model of analytical precision," it does appear that the MAC concluded that M.G.'s plan of care failed to comply with the 60-day review requirement of § 409.43(e) and that this conclusion is supported by substantial evidence in the record. *See Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 350 (4th Cir. 2001) (holding that an agency's explanation for its decision need not be a "model of analytic precision" and that courts must "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned"). Review of the administrative record reflects that the ALJ clearly determined that M.G.'s plan of care was defective under § 409.43(e) because the plan had not been reviewed every 60 days. As the ALJ explained, this finding was based on the fact that the physician's signature on the plan was dated November 20, 2009, more than 60 days after the commencement of the home health services described in the plan. On appeal, the MAC squarely rejected plaintiff's argument that the ALJ's decision concerning the 60-day review requirement was based on an inapplicable regulation that post-dated M.G.'s plan of care. Thus, it is reasonably discernable that the MAC decision adopted the ALJ's conclusion that the plan of care failed to comply with the 60-day review requirement of § 409.43 based on the MAC's approval of the ALJ's reasoning on this ground. *See Int'l Rehab. Scis. Inc. v. Sebelius*, 688 F.3d 994, 1003 (9th Cir. 2012)

(holding that the MAC provided "adequate reasons" for its decision based on the MAC's approval of the reasoning in the underlying ALJ decision denying coverage).

Further, as already noted, the ALJ and the MAC's finding that the plan of care was not reviewed every 60 days is supported by substantial evidence, namely the fact that the physician's signature on the plan was dated November 20, 2009, more than 60 days after the commencement of the home health services described in the plan. Accordingly, even if the MAC's finding that M.G.'s plan of care was not signed by a physician is unsupported by substantial evidence, reversal of the MAC's decision is not warranted because substantial evidence exists to support the MAC's alternative finding that the plan failed to comply with the 60-day review requirement of § 409.43(e).

D. Beneficiary: J.H., Dates of Service: April 25, 2010 – May 26, 2010

Plaintiff argues that the MAC's determination that there was no Medicare coverage for the physical therapy services provided to J.F. must be set aside because the MAC's decision is not supported by substantial evidence in the record. A review of the record demonstrates that the MAC's determination of no-coverage is supported by substantial evidence.

The MAC determined that the physical therapy services provided to treat J.H.'s back pain were not eligible for Medicare coverage because the documentation in the record was inadequate to demonstrate that such services were reasonable or necessary. This conclusion is supported by the substantial record evidence cited in the MAC decision. In this regard, the MAC first observed that J.H.'s documentation did not provide (i) a detailed initial evaluation, (ii) a clear comparison between J.H.'s prior level of functioning and his current level of functioning, or (iii) the goals of therapy. Next, the MAC noted that multiple medical reports reported that J.H. had no back pain and that his reports of pain levels of 4 or 5 out of 10 on other occasions were unreliable because

J.H.'s cognitive impairments made it difficult for him to use a numerical score system. Based on this evidence, the MAC reasonably concluded that the record evidence on the whole did not reflect that the physical therapy services provided to J.H. were medically reasonable or necessary to treat J.H.'s back pain.

E. Beneficiary: R.H., Dates of Service: November 17, 2007 – January 15, 2008

Plaintiff argues that the MAC's determination that there was no Medicare coverage for the first period of skilled nursing services provided to R.H. must be set aside because the MAC did not give a sufficient explanation for its determination and because that determination is not supported by substantial evidence. A review of the record demonstrates that that the MAC sufficiently explained the reasoning for its determination of no-coverage and that the determination is supported by substantial evidence in the record.

The MAC concluded that the skilled nursing services provided to R.H. were not necessary for purposes of observation and assessment of R.H.'s condition. As explained in the MAC decision, this conclusion was based on the fact that the records of nursing visits did not reflect a sufficient likelihood of change in R.H.'s condition to warrant evaluation by skilled nursing personnel, as is required for Medicare coverage under MBPM § 40.1.2.1. Thus, the MAC adequately explained that its no-coverage determination was based on a finding that on the whole the record evidence did not show that there was a sufficient likelihood of change in R.H.'s condition to create a necessity for observation and assessment services by a skilled nurse.

In addition, the records of nursing visits referenced by the MAC decision reflect that there is substantial evidence to support MAC's determination that there was an insufficient likelihood of change in R.H.'s condition to warrant observation and assessment by a skilled nurse. Prior to the commencement of the services at issue, only one record reflects a change in R.H.'s breathing,

weight, and lab results, whereas the remaining nursing visit records reflect that such conditions remained constant. In addition, the nursing records reflect that R.H.'s primary diagnosis of edema persisted throughout the period at issue, as did the use of Lasix to treat R.H.'s edema. It does appear that the nursing notes reflect a greater degree of fluctuation in R.H.'s blood pressure. Yet, in light of the various other indicators of consistency in R.H.'s condition discussed above, the changes in R.H.'s blood pressure readings do not undermine the MAC's conclusion that the record on the whole reflected that observation and assessment were not necessary. Accordingly, the nursing notes cited by the MAC decision constitute substantial evidence to support the MAC's determination that the record disclosed insufficient complications in R.H.'s condition to warrant the provision of observation and assessment services by a skilled nurse.

F. Beneficiary: R.H., Dates of Service: January 16, 2008 – March 15, 2008

Plaintiff argues that the MAC's determination that there was no Medicare coverage for the second period of skilled nursing services provided to R.H. must be set aside because the MAC's determination is not supported by substantial evidence in the record. A review of the record demonstrates that that the MAC's no-coverage determination is supported by substantial evidence.

The MAC concluded that the skilled nursing services provided to R.H. were not necessary for purposes of observation and assessment of R.H.'s condition because there was an insufficient likelihood of change in R.H.'s condition to warrant observation and assessment by a skilled nurse.[12] The records of nursing visits cited by the MAC decision reflect that there is substantial evidence to support this determination. Specifically, the nursing records disclose that R.H.'s vitals,

[12] The MAC decision also determined that the nursing services provided during this period were unnecessary for purposes of patient education and that the occupational therapy, home health aide, and medical social services provided to R.H. were also not eligible for Medicare coverage. Yet, because plaintiff's arguments focus only on the necessity of nursing services for purposes of observation and assessment, review of the MAC's decision here is likewise limited to that ground.

breathing, lab results, weight, and edema remained constant during the second period of skilled nursing services provided to R.H., as was the case during the first period of nursing observation discussed above. Although the physician prescribed two new medications to treat R.H.'s high blood pressure and pain, the nursing report documenting those new prescriptions also noted that R.H.'s daughter would assume primary responsibility over R.H.'s medications. Accordingly, the nursing notes cited by the MAC decision—with respect to both the first and second periods of R.H.'s nursing care—constitute substantial evidence to support the MAC's determination that the record disclosed insufficient complications in R.H.'s condition to warrant the provision of observation and assessment services by a skilled nurse.

G. Beneficiary: C.S., Dates of Service: March 16, 2010 – May 14, 2010

Plaintiff argues that the MAC's determination that there was no Medicare coverage for the various services provided to C.S. must be set aside because the MAC's reasoning marks an arbitrary departure from its decisions in previous cases and is not supported by substantial evidence in the record. A review of the MAC's previous decisions and the record demonstrates that the MAC's no-coverage determination is in harmony with agency precedent and is supported by substantial evidence.

The first ground on which the MAC affirmed the ALJ's no-coverage determination was that the plan of care did not clearly reflect the date that it was reviewed by a physician, which rendered the plan of care invalid pursuant to 42 C.F.R. § 409.43(c)(3). Plaintiff argues that the MAC's invalidation of the plan of care on this ground is an arbitrary departure from the agency's decision in *Landmark Home Health*, M-2009-1209 (H.H.S. February 19, 2010), which held that the physician's failure to date his signature on the plan of care did not invalidate the plan of care. Plaintiff's argument fails because the *Landmark* decision is factually distinguishable from C.S.'s

case. In *Landmark*, the MAC concluded that it was not necessary for the physician to date his signature because the plan of care bore a handwritten date in block 24, "Date [Home Health Agency] Received Signed [Plan of Treatment]." *Landmark* at *5. This was so, the MAC explained, because the presence of the handwritten date in block 24 provided a clear indication of the date that the plan of care was reviewed by the physician, in satisfaction of the requirement in § 409.43 that each review of the plan of care must contain the date of review. Here, the plan of care for C.S.'s services is not dated by the physician and bears only a facsimile header that indicates the date it was returned from the physician's office. Unlike the handwritten date on the plan of care in *Landmark*, the facsimile header on C.S.'s plan of care does not clearly reflect the date that the physician reviewed the plan; it indicates only the date on which the plan of care was faxed by the physician's office. Thus, the MAC's determination that the physician's failure to mark the date on which he reviewed C.S.'s plan of care renders the plan of care deficient is contrary neither to § 409.43(c)(3) nor to the agency's prior application of that regulation in *Landmark*.

The second independent ground on which the MAC affirmed the ALJ's no-coverage determination was that the record did not demonstrate that C.S.'s home health services were reasonable or necessary during the period at issue. Plaintiff argues that this conclusion is not supported by substantial evidence. This argument fails because there is substantial evidence in the record to support the MAC's determination that there was not a sufficient change in C.S.'s condition to warrant the services provided during this period. Specifically, the record reflected that home health services had been resumed because of a stroke suffered by C.S. Yet, as the MAC noted, C.S.'s stroke had occurred seven months before the commencement of the services at issue, and during the interim C.S. had already been admitted to and discharged from home health services after the physician determined that C.S. had reached his maximum functional potential. Further, a

doctor's assessment of C.S. noted that there was no significant change in C.S.'s condition since his last period of home health treatment, and other nursing records made during this period also observed that C.S.'s condition was stable. Thus, the MAC's determination that the home health services provided to C.S. during this period were not medically reasonable or necessary is supported by substantial evidence in the record, namely (i) that C.S. had already received and been discharged from home health services to treat the effects of his stroke and (ii) that C.S. did not exhibit a significant change in his condition since his discharge.

H. Beneficiary: J.S., Dates of Service: February 4, 2009 – April 3, 2009

Plaintiff argues that the MAC's determination that there was no Medicare coverage for the physical therapy services provided to J.S. must be set aside because the MAC's determination did not apply the correct legal standard. A review of the MAC decision demonstrates that that the MAC's no-coverage determination applied the correct legal standard in assessing whether the physical therapy services were covered by Medicare.

The MAC concluded that the record did not support the need for physical therapy services because the plan of care did not document J.S.'s prior level of function or the goals of therapy in terms of objective measurements and because multiple physical therapy evaluations failed to reflect any objective tests or measurements relating to J.S.'s functional status or treatment goals.[13] In reaching this conclusion, the MAC explained that MBPM § 40.2.2.A provides that skilled physical therapy assessment services that are entitled to Medicare coverage include "objective tests and measurements such as, but not limited to, range of motion, strength, balance, coordination, endurance, or functional ability." The MAC decision then observed that the majority of the

[13] It also appears that the MAC determination of no coverage with respect to J.S.'s physical therapy services was based on the additional, independent ground that the services provided constituted repetitious exercises, which are excluded from coverage under 42 C.F.R. § 403.33(d)(13). Plaintiff does not challenge that ground for the MAC's decision.

physical therapy records did not reflect any objective tests or measurements relating to J.S.'s functional status or treatment goals. Thus, the MAC concluded that, pursuant to MBPM § 40.2.2.A, the physical therapy assessment services provided to J.S. did not consist of objective tests and measurements and were thus not covered by Medicare.

A plain reading of MBPM § 40.2.2.A confirms that the MAC correctly applied the regulation in evaluating whether the treatment goals and services provided to J.S. consisted of objective tests and measurements. *See id.* ("Skilled rehabilitation services concurrent with the management of a patient's care plan *include objective tests and measurements* such as, but not limited to, range of motion, strength, balance, coordination, endurance, or functional ability.") (emphasis added). Furthermore, the Fourth Circuit has made clear that the MAC's view of its own Medicare regulations is entitled to "controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Almy v. Sebelius*, 679 F.3d 297, 302 (4th Cir. 2012) (quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945)). Plaintiff has cited no persuasive basis on which to conclude that MAC's application of MBPM § 40.2.2.A here is inconsistent with the regulation. Accordingly, MAC's determination that the physical therapy services provided to J.S. did not constitute coverable skilled services correctly applied the relevant legal standards and must be upheld.

I. Beneficiary: R.S., Dates of Service: December 14, 2008 – February 11, 2009

Plaintiff argues that the MAC's determination that there was no Medicare coverage for the physical therapy services provided to R.S. must be set aside because the MAC's determination is unsupported by substantial evidence in the record. A review of the record demonstrates that that the MAC's no-coverage determination is supported by substantial evidence.

The physical therapy visit at issue consisted of assessing R.S.'s lymphedema, educating R.S. about her disease process, and educating nursing staff about multi-layer bandaging for lymphedema management. The MAC concluded that the physical therapy visit was not covered by Medicare on two grounds, each of which is supported by substantial evidence. First, the MAC affirmed the ALJ's finding that the physical therapy services were not reasonable or necessary because they were duplicative of the skilled nursing services provided to R.S. during the period at issue. In this respect, the record reflects that R.S. also received skilled nursing services that included providing wound care, assessing R.S.'s lymphedema, applying compression foot and leg wraps, and educating R.S. about the signs and symptoms of infection, which were all covered by Medicare. This evidence amply supports the MAC's finding that the physical therapy services provided to R.S.—namely, assessing R.S.'s lymphedema and educating R.S. about her disease process—were duplicative of the skilled nursing services already being provided to R.S.

Second, the MAC concluded that the physical therapy service consisting of educating nursing staff about multi-layer bandaging for lymphedema management was not covered by Medicare because MBPM § 40.2.1(d) excludes coverage for therapy visits "solely to train other [staff]." As the record evidence discussed above makes clear, all of the other physical therapy services provided to R.S. were duplicative and thus not covered by Medicare. Thus, the MAC was correct to determine that MBPM § 40.2.1(d) precluded coverage when the only non-duplicative, potentially coverable service provided in the physical therapy visit was to teach the nursing staff how to control and bandage lymphedema.

J. Beneficiary: R.S., Dates of Service: October 10, 2009 – December 8, 2009

Plaintiff argues that the MAC's determination that there was no Medicare coverage for the occupational therapy services provided to R.S. must be set aside because the MAC's determination

applied incorrect legal principles. A review of the MAC decision demonstrates that that the MAC's no-coverage determination applied the correct legal principles.

The MAC concluded that the occupational therapy services related to increasing R.S.'s arm strength were not covered by Medicare because such services were not medically reasonable or necessary. In reaching this conclusion, the MAC explained that MBPM § 40.2.4.1 provides that occupational therapy services are entitled to coverage only when such services are reasonable and necessary "because of the patient's condition."[14] The MAC decision then observed that the goals of R.S.'s occupational therapy included strengthening R.S.'s arms to an objective measurement of 3/5, yet none of the notes from R.S.'s treatment included any measurements of R.S.'s arm strength. Thus, the MAC concluded that the record was insufficient to show that the occupational therapy services were reasonably tailored to treat the deficit in R.S.'s arm strength, as is required for coverage under MBPM § 40.2.4.1. *See* MBPM § 40.2.4.1 (providing that "the skills of an occupational therapist to . . . implement an occupational therapy program are covered when they are reasonable and necessary because of the patient's condition"). Plaintiff has cited no persuasive ground on which to conclude that the MAC improperly applied MBPM § 40.2.4.1 in determining that the treatment record was insufficient to show that the occupational therapy was reasonably designed to treat R.S.'s objectively measurable arm strength deficit.

The MAC also found that the occupational therapy services related to increasing R.S.'s independence in activities of daily living were not covered by Medicare because such services were not reasonable or necessary. Plaintiff argues that the MAC improperly based its determination that the occupational therapy was not reasonable or necessary on the retrospective

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[14] *See also* 42 C.F.R. § 409.44(c)(1) ("[O]ccupational therapy services must relate directly and specifically to a treatment regimen . . . that is designed to treat the beneficiary's illness or injury.").

observation that R.S. did not demonstrate any improvement during the treatment. This argument fails; as the ALJ specifically concluded, and the MAC affirmed, the occupational therapy services related to increasing R.S.'s independence in activities of daily living were not reasonable or necessary because the record did not show that such services were provided with a reasonable expectation of improvement, as is required for coverage under MBPM § 40.2.1(d)(1). The MAC found that the reasonable expectation standard had not been met because the record reflected that the occupational therapy services remained repetitive despite a lack of improvement in R.S.'s condition. Thus, the MAC did not base its conclusion that the occupational therapy services were not medically reasonable or necessary solely on the fact that R.S. did not exhibit improved independence in activities of daily living. Rather, the MAC and the ALJ properly applied MBPM § 40.2.1(d)(1) and concluded that such services were not provided with a reasonable expectation of improvement based on the fact that the same, repetitive therapy continued to be provided despite a lack of improvement in the patient's condition.

VI.

Plaintiff next argues that the MAC's conclusions that plaintiff is not entitled to a limitation of liability pursuant to 42 U.S.C. § 1395pp or a waiver of recoupment pursuant to 42 U.S.C. § 1395gg should be set aside because these determinations apply incorrect legal standards and are unsupported by substantial evidence. The MAC's liability determinations with respect to each of these statutes are examined separately below.

A.

Section 1395pp of the Medicare Act provides that a healthcare provider is not liable for repaying Medicare payments for services that have been deemed not to be medically reasonable or necessary if the provider "did not know, and could not reasonably have been expected to know,

that payment would not be made." 42 U.S.C. § 1395pp(a). The regulations further explain that "[i]t is clear that the provider . . . could have been expected to have known that the services were excluded from coverage on the basis of . . . [i]ts receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives." 42 C.F.R. § 411.406(e); *see also* Medicare Claims Processing Manual ("MCPM") Ch. 30 § 40.1.2 (stating that "[a] provider is always considered to have prior knowledge, and no Medicare payment will be made to any provider for any claim, if previous notification was given . . . that the claim would be denied," including the forms of notification listed in 42 C.F.R. § 411.406). In short, as courts have held, Medicare-certified providers can be expected to know that certain services are not covered by Medicare based on their "constructive notice" of the criteria for coverage in the Medicare regulations and manuals.[15]

These principles confirm that the MAC's determination that plaintiff was not entitled to a limitation of liability under § 1395pp applied correct legal standards and is supported by substantial evidence. As the MAC decision observed, the MAC's determinations that certain services provided by plaintiff were not medically reasonable or necessary were each based on guidance from publicly available statutes, regulations, and CMS manual provisions that were in effect when plaintiff provided the services. Thus, it was reasonable for the MAC to conclude that plaintiff had constructive knowledge of the requirements for Medicare coverage on which the MAC relied and thus that plaintiff could have been expected to know that Medicare would not pay for the services that fell outside of the limitations on coverage reflected in those requirements.

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[15] *See, e.g., Vitreo Retinal Consultants of the Palm Beaches, P.A. v. U.S. Dep't of Health & Human Servs.*, 649 F. App'x 684, 697 (11th Cir. 2016); *KGV Easy Leasing Corp. v. Leavitt*, 413 F. App'x 966, 968 (9th Cir. 2011); *Maximum Comfort Inc. v. Sec'y of Health & Human Servs.*, 512 F.3d 1081, 1088 (9th Cir. 2007); *Superior Home Health Servs., L.L.C. v. Azar*, No. 5:15-CV-00636-RCL, 2018 WL 3717121, at *16 (W.D. Tex. Aug. 3, 2018); *Galindo v. Burwell*, No. CV M-16-257, 2017 WL 10309904, at *27 (S.D. Tex. Sept. 7, 2017), *report and recommendation adopted*, No. CV M-16-257, 2018 WL 4689610 (S.D. Tex. Sept. 28, 2018).

Seeking to avoid this conclusion, plaintiff argues that it could not have been expected to know that Medicare would not pay for the services at issue because it was not clear and obvious that Medicare did not cover those services. Put another way, plaintiff argues that the CMS guidance on which the MAC relied was not sufficiently clear to put plaintiff on notice that its Medicare claims would be denied. This argument fails; as courts have sensibly recognized, the test advocated by plaintiff finds no support in the regulations, which state that providers are expected to know that certain services are not covered by Medicare based on their constructive notice of the criteria for coverage in the Medicare regulations and manuals. *See, e.g.*, *Galindo v. Burwell*, No. CV M-16-257, 2017 WL 10309904, at *27 (S.D. Tex. Sept. 7, 2017), *report and recommendation adopted*, No. CV M-16-257, 2018 WL 4689610 (S.D. Tex. Sept. 28, 2018). Plaintiff cites no persuasive authority to support the proposition that the agency must make the demanding showing that the clarity of the Medicare guidance makes it obvious that certain services are not covered. To the contrary, what the regulations make clear and obvious is that a Medicare-certified provider's constructive notice of the criteria for coverage in Medicare guidance is sufficient to demonstrate that the provider "could have been expected to have known that the services were excluded from coverage." 42 C.F.R. § 411.406(e).[16]

[16] The cases relied upon by plaintiff do not hold to the contrary. In each of the two cases plaintiff cites, the court held that the provider was entitled to limitation of liability under § 1395pp because the Medicare rules on which the MAC relied to deny coverage were not in effect when the services at issue were provided and thus the provider could not be deemed to have constructive knowledge. *See Caring Hearts Pers. Home Servs., Inc. v. Burwell*, 824 F.3d 968, 970 (10th Cir. 2016) (observing that "the agency held that the firm knew or should've known its conduct was unlawful only in light of regulations that were then but figments of the rulemakers' imagination, still years away from adoption"); *Cypress Home Care, Inc. v. Azar*, 326 F. Supp. 3d 307, 316 (E.D. Tex. 2018) ("[T]he Council applied the 2013 requirements to the beneficiaries in this case, all of whom received treatment in the 2008–2010 time period."). These cases are therefore distinguishable and unpersuasive here. In sharp contrast with those cases, the Medicare rules on which the MAC relied to deny coverage here were in effect at the time that plaintiff provided the services at issue. Unlike the Medicare providers in those cases, plaintiff here is therefore properly deemed to have constructive notice of the criteria for Medicare coverage that precluded Medicare payment in this case.

Accordingly, the MAC correctly determined that plaintiff is not entitled to a limitation of its liability to reimburse the sums paid to plaintiff by Medicare for services that the MAC determined were not medically reasonable and necessary under the Medicare statute and regulations.

B.

Section 1395gg of the Medicare Act provides that the Secretary may waive recoupment where the provider was "without fault" when it received overpayment. 42 U.S.C. § 1395gg(b). The Medicare Financial Management Manual ("MFMM") makes clear that the provider is deemed to be at fault for causing an overpayment if Medicare paid the provider for services that the provider should have known were not covered by Medicare. MFMM Ch. 3 § 90.1(H). The MAC found that plaintiff was not entitled to a waiver of recoupment because plaintiff should have known that the services for which the MAC denied coverage were not covered by Medicare. For the reasons already stated, *supra* part VI.A, the MAC's determination that plaintiff should have known that the services at issue fell outside the requirements for Medicare coverage applied the correct legal standards and is supported by substantial evidence.[17] Accordingly, plaintiff is not entitled to a waiver of recoupment for the sums paid to plaintiff by Medicare for services that the MAC determined were not covered by Medicare.[18]

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[17] This provision of the MFMM incorporates by reference the criteria set forth in MCPM § 40.1.2 for determining whether a provider should have known that services would not be covered by Medicare. *See* MFMM § 90.1(H)(2). MCPM § 40.1.2, in turn, provides that the various forms of notification listed in 42 C.F.R. § 411.406 provide sufficient evidence that the provider should have known that the services or items would be denied. Accordingly, the analysis whether plaintiff should have known that the services at issue were not covered by Medicare is identical under the waiver provisions of § 1395pp and § 1395gg and need not be addressed again here.

[18] It is worth noting that the Fourth Circuit, along with other courts of appeal, have held that a provider is not eligible for waiver of recoupment under § 1395gg. *See MacKenzie Med. Supply, Inc. v. Leavitt*, 506 F.3d 341, 349 (4th Cir. 2007) (holding that overpayment waiver mechanism in § 1395gg applies only to individual Medicare beneficiaries, not Medicare providers); *see also Visiting Nurses Ass'n of Southwestern Indiana, Inc. v. Shalala*, 213 F.3d 352, 355–59 (7th Cir. 2000) (same); *Kraemer v. Heckler*, 737 F.2d 214, 216 (2d Cir. 1984) (noting individual/provider distinction between §§ 1395gg and 1395pp). Yet, in light of the fact that the MAC did not rely on this principle in determining that plaintiff was not entitled to waiver of recoupment under § 1395gg, it is

VII.

In sum, for the reasons stated above, the MAC's determination that plaintiff was overpaid for ineligible Medicare claims is in accordance with the law and supported by the record evidence, and it is neither arbitrary nor capricious. Accordingly, because plaintiff has failed to show that there is any persuasive ground to reverse the MAC's decision under the deferential standards of review prescribed by the APA, summary judgment must be entered in favor of defendant.

An appropriate order will issue.

Alexandria, Virginia
June 17, 2019

/s/
T. S. Ellis, III
United States District Judge

inappropriate to uphold the MAC's determination on this additional ground. *See Cone Mills Corp. v. N. L. R. B.*, 413 F.2d 445, 452 (4th Cir. 1969) (holding that a reviewing court may not affirm an agency's decision on the basis of "appellate counsel's post hoc rationalizations for agency action" and that an agency's decision "will be upheld, if at all, on the same bases articulated in the order by the agency itself").